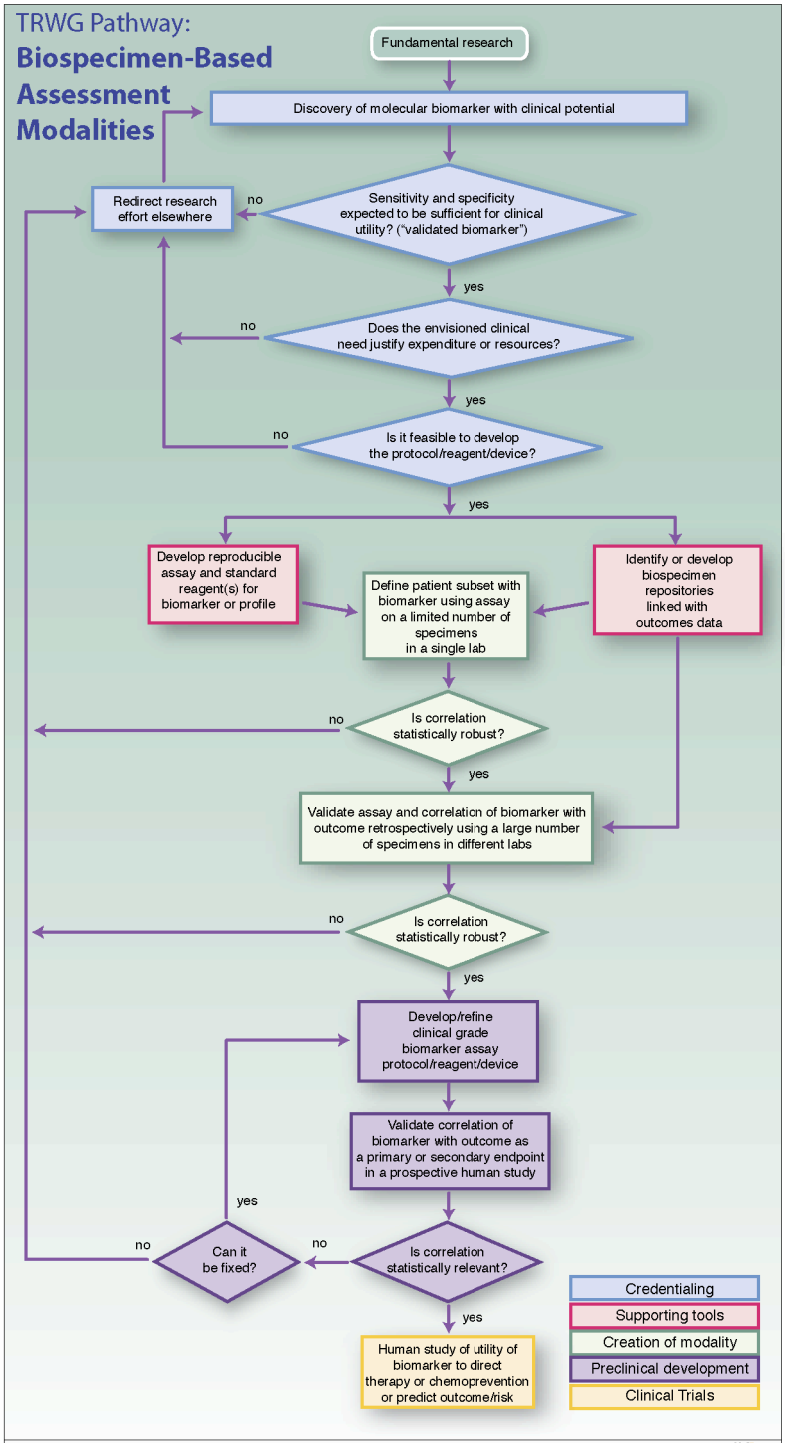
TRWG Pathway:
Biospecimen-Based Assessment Modalities
Fundamental research
Discovery of molecular biomarker with clinical potential
Sensitivity and specificity expected to be sufficient for clinical utility? ("validated biomarker")
no
Redirect research effort elsewhere
yes
Does the envisioned clinical need justify expenditure or resources?
no
yes
Is it feasible to develop the protocol/reagent/device?
no
yes
Develop reproducible assay and standard reagent(s) for biomarker or profile
Define patient subset with biomarker using assay on a limited number of specimens in a single lab
Identify or develop biospecimen repositories linked with outcomes data
Is correlation statistically robust?
no
yes
Validate assay and correlation of biomarker with outcome retrospectively using a large number of specimens in different labs
Is correlation statistically robust?
no
yes
Develop/refine clinical grade biomarker assay protocol/reagent/device
Validate correlation of biomarker with outcome as a primary or secondary endpoint in a prospective human study
Is correlation statistically relevant?
no
yes
Can it be fixed?
yes
no
Human study of utility of biomarker to direct therapy or chemoprevention or predict outcome/risk
Credentialing
Supporting tools
Creation of modality
Preclinical development
Clinical Trials